K132813
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TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 730-5000

FEB - 6 2014

510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

1. **SUBMITTER'S NAME:**
   Toshiba America Medical Systems, Inc.

2. **ADDRESS:**
   2441 Michelle Drive
   Tustin, CA 92780-2068

3. **ESTABLISHMENT REGISTRATION:**
   2020563

4. **CONTACT PERSON:**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000

5. **DATE PREPARED:**
   January 9, 2014

6. **TRADE NAME(S):**
   Dual Energy System Package, CSDP-001A

7. **COMMON NAME:**
   System, X-ray, Computed Tomography

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR 892.1750)

9. PRODUCT CODE / DESCRIPTION:
90JAK – System, Computed Tomography

10. PERFORMANCE STANDARD:
None

11. PREDICATE DEVICES:

Product	Marketed by	510(k) Number	Clearance Date
Discovery CT 750HD	GE Healthcare	K120833	June 12, 2012
Brilliance Dual Energy Option	Philips Medical Systems, Inc.	K090462	June 23, 2009
syngo Dual Energy with extended functionality	Siemens Medical Solutions USA, Inc.	K083524	April 1, 2009

12. DEVICE DESCRIPTION:
Dual Energy System Package, CSDP-001A, consists of three software packages intended to be used on Toshiba CT systems which allows for the acquisition of two CT images of the same anatomical location using different tube voltages and/or tube currents during two tube rotations.

CSDP-001A/1 (Dual Energy System) allows the same region to be scanned at two different tube voltages and tube currents and permits the CT values and ratio in the selected region to be measured based on the two image data sets obtained, providing information that is useful for identifying materials.

CSDP-001A/2 (Dual Energy Raw Data Analysis) allows monochromatic images to be generated and permits images in which contrast enhancement is visualized to be generated based on the datasets acquired by scanning the same positions with different tube voltages, making it possible to perform analysis.

CSDP-001A/3 (Dual Energy Composition Analysis) reads data acquired by scanning the same positions with different tube voltages and extracts suspected uric acids from the acquired images.

13. INDICATIONS FOR USE:

The Dual Energy System allows the system to acquire two CT images of the same anatomical location using distinct tube voltages and/or tube currents during two tube rotations. The x-ray dose will be the sum of the dose of each tube rotation at its respective tube voltage and current. Information regarding the material composition of various organs, tissues, and contrast materials may be gained from the differences in x-ray attenuation between these distinct energies.

This information may also be used to reconstruct images at multiple energies within the available spectrum, and to reconstruct basis images that allow the visualization and analysis of anatomical and pathological materials.

The visualization of the differentiation between uric acid and non-uric acid stones greater than 3mm and the visualization of uric acid presence within surrounding anatomical structures is provided with the Dual Energy system. When used by a qualified physician, a potential application is to determine the course of treatment.

Performance of this device may be affected by body size and motion artifacts.

14. SUBSTANTIAL EQUIVALENCE:

The **Dual Energy System Package, CSDP-001A** is substantially equivalent to the Discovery CT750HD, the Brilliance Dual Energy Option and the syngo Dual Energy with extended functionality.

Dual Energy System Package, CSDP-001A, performs in a manner similar to the predicate devices in that these systems allow for the acquisition of two CT images of the same anatomical location using different tube voltages and/or currents and when the images are combined they can be used for the visualization and further analysis of anatomical and pathological structures. The subject device accomplishes image acquisition using two rotations with one tube, rather than in one tube rotation as utilized by the predicate devices. The method of kidney stone characterization also differs from that used by Discovery CT750HD in that an image based two material decomposition method is used in the subject device, whereas, the predicate device uses a spectrum of effective atomic number.

15. SAFETY:

This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards.

16. NON-CLINICAL TESTING

Verification and validation testing, hazard analysis and performance testing conducted through bench and clinical testing are included in this submission to support the claims and indications.

Uric Acid Analysis

Studies using a water phantom with known regions of uric acid adjacent to calcium inserts and a custom anthropomorphic hand phantom containing varying concentrations of monosodium urate were conducted to confirm that the software can provide visualization of uric acid within surrounding structures.

Monochromatic Imaging

Beam Hardening Reduction

A custom phantom designed to simulate a beam hardening artifact situation was utilized to confirm that a reduction in beam hardening artifacts was possible using the Dual Energy System Package as compared to a single energy scan.

Contrast-Noise Ratio (CNR) Improvement

A custom phantom containing tubes filled with varying concentrations of water/iodine was scanned using the Dual Energy System Package to generate monochromatic images. The software selected images with ideal contrast to noise ratio and it was demonstrated that, in comparison single energy scans, the monochromatic images had improved contrast-noise ratio.

Kidney Stone Analysis

Kidney Stones in Tissue

Kidney stones of known material were inserted into a representative abdominal phantom and scanned with the Dual Energy System Package. Results of the study demonstrated that the software is able to differentiate between uric acid and non-uric acid kidney stones within a representative abdominal phantom.

Mixed Stones

Vials consisting of pure and mixed kidney stones were inserted into a phantom and scanned using the Dual Energy System Package. Analysis of the results concluded that the pure uric acid stones within the mixture could be discriminated from the other stones.

Body Size

Vials consisting of kidney stones of known composition were inserted into a phantom designed to imitate various human body sizes. The phantom was scanned using the software and analysis of the results concluded that the pure uric acid stones could be discriminated from the other stones.

Motion

Frequency of patient motion artifacts was evaluated using CT image data obtained from cases with and without breathing. The data was scored on level of motion artifacts and the results of the study concluded that the ratio of motion artifacts that could have a significant effect on the images was nearly non-existent.

Iodine Map
A water phantom containing tubes filled with diluted contrast medium of varying concentrations was scanned using Dual Energy volume scan. Iodine maps were generated by the software and it was concluded that there was no significant difference between the iodine map values and the actual iodine concentrations.

Additionally, software documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission.

17. CLINICAL TESTING

Uric Acid Analysis
A patient with suspicion of gout in the right hand was scanned twice using low and high tube voltage. The volumes were loaded to the Dual Energy analysis software and the resultant images displayed high-lighted regions of suspected uric acid. One of the suspected regions was surgically extracted and confirmed to be uric acid by polarized microscopy analysis.

Kidney Stone Analysis
A total of twelve (12) patients were scanned using a Toshiba CT system with the Dual Energy System Package. Stone analysis of the resultant images was performed and it was determined that the system was able to detect pure uric acid stones greater than 3 mm with a 75% sensitivity and an 83.3% specificity. Stone compositions were confirmed using polarized microscopy.

Iodine Map
One representative clinical data set of a patient with suspicion of ischemia in the small bowel was acquired by Dual Energy software package and an iodine map was output by the software. Analysis of the resultant images demonstrated that visualization of the ischemic region is possible due to the lack of contrast enhancement in the lower perfusion region.

18. CONCLUSION

Dual Energy System Package, CSDP-001A, performs in a manner similar to and is intended for the same use as the predicate devices. Based upon the data presented in this submission including application of design controls and performance data, Toshiba America Medical Systems, believes that **Dual Energy System Package, CSDP-001A**, is substantially equivalent in safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2014

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K132813
Trade/Device Name: Dual Energy System Package, CSDP-001A
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 9, 2014
Received: January 10, 2014

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132813

Device Name: **Dual Energy System Package, CSDP-001A**

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Performance of this device may be affected by body size and motion artifacts.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)